



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/567,739

03/27/2006

Makoto Noami

2006_0106A

7704

513

7590

06/12/2009

WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

BUIE, NICOLE M

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

06/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,739	Applicant(s) NOAMI ET AL.	
	Examiner NICOLE M. BUIE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-16 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-16 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20081216</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 03/16/2009 has been entered. Claims 1, 3-16, and 19 remain pending in the application. The support for the composition is obtained by copolymerizing only a polyvinyl alcohol can be found at page 12, lines 9-25.

Response to Arguments

Applicant's arguments filed 03/16/2009 have been fully considered and are substantially persuasive. The following comments apply:

A) Applicants' amendment to claim 11 does not overcome the 112, second paragraph rejection. Claim 11 which depends on claims 1 and 6-9 recites a partially hydrolyzed polyvinyl alcohol, however claims 1 and 6-9 do not recite a partially hydrolyzed polyvinyl alcohol.

B) Applicants' argument that in Synthesis Example 4 as taught by Hoshi has two PVA polymers (P7) is persuasive. Therefore Synthesis Example 4 is withdrawn from the previous rejection. However, since Hoshi teaches that polyvinyl alcohol and/or its derivative may be used [0003], it is anticipated to replace PVA-SH of Synthesis Examples 1-3 with polyvinyl alcohol.

C) Applicants' argument that Saliba does not teach a composition wherein the composition is obtained by copolymerizing only a polyvinyl alcohol having an average polymerization degree of 200 to 900 and at least one or more polymerizable vinyl monomers (P8) is not persuasive. Saliba was used as an evidentiary reference to show that PVA compositions are known to be used as binders. The purpose of the binder is intended use and does not have any patentable weight.

Comment [M1]: do you mean that synthesis example 4 is no longer relied upon as a foundation for rejection? I don't understand the intent of this remark. Also, what is meant by the next sentence? PVA-SH is a polyvinyl alcohol, ostensibly a mercaptan group-terminated polyvinyl alcohol where the mercaptan group becomes the initiator for the reaction with the vinyl monomers. Their statement that their claimed polymer is structurally different for PVA-SH is completely unfounded because there is not enough structure provided from which any differences might be inferred.

D) Applicants' argument that Sainen does not teach only the copolymerization of polyvinyl alcohol and at least one vinyl monomer (P9) is not persuasive. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Sainen teaches one polyvinyl alcohol may be used [0016].

Comment [M2]: that's not what they said. they stated that a PVA polymer with the specified number of repeat units is not disclosed and it is this argument to which you should respond. Basically, their argument is that neither of the references exemplify their invention but their broader disclosures do say that the PVA component can have 500 to 2000 repeat units so the references would definitely still apply. The only question is whether you should maintain a 102 rejection or re-state under 103- you could still make it final- and that decision is rooted in the concept of sufficient specificity- see the MPEP. I'll make it your call as to whether the 102 rejection is maintained or if a change to 103 is made.

E) Applicants' argument that the coating agent comprising the resin composition containing the copolymer is not described in Sainen (P9) is not persuasive. Sainen teaches that the composition is a coating (claim 1).

F) Applicants' showing of unexpected results does not overcome a rejection based on anticipation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 recite the limitation "partially hydrolyzed polyvinyl alcohol". There is insufficient antecedent basis for this limitation in the claim. For the purpose of this Office Action, "partially hydrolyzed polyvinyl alcohol" will be treated as "polyvinyl alcohol".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-15, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763).

Regarding claims 1, 3, 5, 6, and 12, Hoshi et al. discloses a resin composition, characterized in that said composition is obtained by copolymerizing PVA-SH having an average polymerization degree of 2000 or less (Synthesis Examples 1-3), wherein specific average polymerization degrees of "500" is disclosed in Synthesis Examples 1-3 (as compared to 1300 or less, or 900 or less, or 200-600 as required by said claim), and two polymerizable vinyl monomers (i.e. methacrylic acid and methyl methacrylate or acrylic acid and methyl methacrylate) in a weight ratio of each is disclosed in Table 4, wherein the quantities of each fall squarely in the specified ranges. The PVA-SH could be substituted with polyvinylalcohol [0003].

Regarding claim 4, Hoshi et al. discloses a resin composition wherein a polyvinyl alcohol is a partially hydrolyzed polyvinyl alcohol ([0025], Examples 1-3).

Regarding claims 7-9, Hoshi et al. discloses a composition wherein an unsaturated carboxylic acid is acrylic acid, methacrylic acid, fumaric acid, maleic acid, or itaconic acid, or salts thereof ([0029], [0030]), and an unsaturated carboxylic acid ester is methyl methacrylate, methyl acrylate, ethyl methacrylate, ethyl acrylate, butyl methacrylate, butyl acrylate, isobutyl methacrylate, isobutyl acrylate, cyclohexyl methacrylate, cyclohexyl acrylate, 2-ethylhexyl methacrylate, 2-ethylhexyl acrylate, hydroxyethyl methacrylate, hydroxyethyl acrylate, an ester of polyethylene glycol and methacrylic acid, an ester of polyethylene glycol and acrylic acid, or an ester of polypropylene glycol and acrylic acid [0031].

Regarding claims 10 and 11, Hoshi et al. discloses a composition wherein the weight ratio of acrylic acid and methyl methacrylate in the copolymerization is 0.25 (5/20), 0.43 (7.5/17.5) (See Examples E-2001 to E-2006 of Table 2 and Examples E-4001 to E-4006 of Table 4).

Regarding claim 13-15, Hoshi et al. discloses a coating agent comprising a resin composition for medicines, animal drugs or foods ([0045]-[0048]).

Claim 16 is rejected under 35 U.S.C. 102(a) as being anticipated by Hoshi et al. (US 2003/0166763) as applied to claim 1 above and in further in view of evidence of Saliba et al. (US 2003/0059649).

Regarding claim 16, Hoshi et al. discloses a binder comprising a resin composition wherein a polyvinyl alcohol copolymers are binders in coating compositions as evidenced by Saliba et al. [0043].

Claims 1 and 3-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation).

Regarding claims 1-3 and 12, JP '383 discloses a resin composition, characterized in that said composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 500-2000 [0016] (as compared to 1300 or less, 900 or less, or 200-600 as required by said claim) and at least one or more polymerizable vinyl monomer(s) in a weight ratio of approximately 2:5 to 2:1 [0018] (as compared to 6:4 to 9:1 as required by said claim).

Regarding claim 4, JP '383 discloses a composition wherein a polyvinyl alcohol is a partially hydrolyzed polyvinyl alcohol (The degree of saponification is 93-99.9 mole%.) [0016].

Regarding claim 5, JP'383 discloses a composition wherein a polymerizable vinyl monomer is an unsaturated carboxylic acid (i.e. acrylic acid) (Example 4), an unsaturated carboxylic acid ester [0011], an unsaturated amide [0013], or an aromatic vinyl [0012].

Regarding claims 6-9, JP '383 discloses a composition wherein a composition is obtained by copolymerizing an unsaturated carboxylic acid (i.e. acrylic acid, methacrylic acid, crotonic acid, maleic acid, itaconic acid) [0013] and an unsaturated carboxylic acid ester (i.e. methyl methacrylate, ethyl methacrylate, butyl methacrylate, cyclohexyl methacrylate) ([0011].

Regarding claim 10, JP '383 discloses a composition wherein the weight ratio of acrylic acid and methyl methacrylate in the copolymerization is 0.5:9.5 ([0028]) (as compared to 3:7 to 0.5:9.5 as required by said claim).

Regarding claims 11, JP '383 discloses a composition characterized in that a composition is obtained by copolymerizing a polyvinyl alcohol having an average

Art Unit: 1796

polymerization degree of 500-2000 [0016] (as compared to 300 to 500 as required by said claim).

Regarding claim 13, JP '383 discloses a coating agent comprising a resin composition [0001].

Regarding claim 14, JP '383 discloses a coating agent for drugs or food [0002].

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Sainen Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) and in further view of evidence of Saliba et al. (US 2003/0059649).

Regarding claim 16, JP '383 discloses a binder comprising a resin composition wherein a polyvinyl alcohol copolymers are binders in coating compositions as evidenced by Saliba et al. [0043].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1796

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) as applied to claim 1 above in view of Keith et al. (US 4,432,965).

Regarding claim 15, JP '383 discloses a composition as shown above in claim 1.

However, JP '383 does not disclose a medicine, an animal drug, an agricultural chemical, a fertilizer or a food which is coated with a coating agent. Keith et al. teaches drugs coated with polyvinyl alcohol compositions (C11-21). JP '383 and Keith et al. are analogous art concerned with the same field of endeavor, namely polyvinyl alcohol compositions for coating drugs. It would have been obvious to one of ordinary skill in the art at the time of invention to coat drugs of Keith et al. with a composition of JP '383, and the motivation to do so would have been as Jordan et al. suggests adjust the rate of release of the drug (C1/L36-53).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saiden Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation).

Regarding claims 17 and 18, JP '383 discloses a resin composition, characterized in that said composition is obtained by copolymerizing a polyvinyl alcohol having an average polymerization degree of 500-1,000 [0016] with a specific polymerization degree of 500 [0025] (as compared to 900 or less as required by said claim), and at least one or more polymerizable vinyl monomers such as an unsaturated carboxylic acid (i.e. acrylic acid, methacrylic acid, crotonic acid, maleic acid, itaconic acid) [0013] and an unsaturated carboxylic acid ester (i.e.

Art Unit: 1796

methyl methacrylate, ethyl methacrylate, butyl methacrylate, cyclohexyl methacrylate) ([0011] in a weight ratio of approximately 2:5 to 2:1 [0018] (as compared to 6:4 to 9:1 as required by said claim), and a copolymer of a polyvinyl alcohol having an average polymerization degree of 1,000-2,000 [0016] with a specific average polymerization degree of 1700 [0025] (as compared to 1500 or 1700 as required by said claim) with comonomers, such as methacrylate esters, aromatic vinyl system, monomer which has functional groups (i.e. methacrylic acid, crotonic acid, itaconic acid) ([0011]-[0013]).

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sainen Chemical Industry Co., Ltd. (JP 2002-105383, see machine translation for citation) as applied to claims 17 and 18 above, and further in view of Keith et al. (US 4,432,965).

Regarding claims 19 and 20, JP '383 discloses a resin composition as shown above in claims 17 and 18. JP '383 discloses a packing material for drugs [0002].

Art Unit: 1796

However, JP '383 does not disclose a coating agent for tablets or granules. Keith et al. teaches a tablet coated with a polyvinyl alcohol composition (Abstract, C1/L11-21). JP '383 and Keith et al. are analogous art concerned with the same field of endeavor, namely polyvinyl alcohol compositions for coating drugs. It would have been obvious to one of ordinary skill in the art at the time of invention to coat drugs of Keith et al. with a composition of JP '383, and the motivation to do so would have been as Jordan et al. suggests adjust the rate of release of the drug (C1/L36-53).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE whose telephone number is (571)270-3879.

The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. B./
Examiner, Art Unit 1796
6/9/2009

/Marc S. Zimmer/

Primary Examiner, Art Unit 1796

Formatted: Right